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## The origins of regulatory science for medical devices

The thalidomide scandal provided huge impetus for the development of systems to regulate new drugs, in the 1960s, but legislation concerning the evaluation of medical devices was not introduced until the 1990s. Despite well-publicised problems with cardiac devices, metal-on-metal hips, surgical meshes and breast implants, the regulatory frameworks that govern pharmaceutical products and medical devices remain quite different. From clinical and ethical perspectives the requirements for evidence and transparency should be the same. The historical traditions of surgical interventions may have contributed to professional attitudes that favour innovation and that accord status to early adopters, but a new subspecialty interest is emerging in the science of the assessment and evaluation of the safety, effectiveness, quality, and performance of devices. The logical goal should be global regulatory convergence, able to adapt with shared standards to challenges such as those now posed by 3-D printing, wearables, artificial intelligence, and remote monitoring